UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,692	11/21/2003	Songzhu An	018781-009530US	1902

7590 07/14/2006

BANNER & WITCOFF
1001 G STREET N.W.
ELEVENTH FLOOR
WASHINGTON, DC 20001

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,692	AN ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11 and 20-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11, 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 8 to 11 and 20 to 32 are pending in the instant application. Claim 8 has been amended, claims 1 to 7 and 12 to 19 have been canceled and claims 20 to 32 have been added as requested by Applicant in the correspondence filed 14 April of 2006.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 8 to 11, 20 to 24 and 26 to 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for those reasons of record as applied to claims 8 to 11 in section 4 of the office action mailed 14 October of 2005. As stated therein, these claims encompass a binding assay that can employ a nucleic acid encoding a "TGR183" protein having other than the entire amino acid sequence presented in SEQ ID NO:6 of the instant application. In fact, claim 8 only requires 20 amino acids from the 346 residue long amino acid sequence presented in SEQ ID NO: of the instant application. However, the instant specification does not provide the guidance needed to produce a "TGR183" polypeptide that "is activated by nicotininc acid" comprising anything less than the entire amino acid sequence presented in SEQ ID NO:6.

Applicant has asserted that a protein of the instant invention belongs to a well characterize protein family all of whose members have a common basic structure and that it is the prior art which provides the guidance needed to predictably alter SEQ ID

NO:6 by as much as 30% with a reasonable expectation that the resulting protein will produce an authentic response. It has been well established in the art of G protein-coupled receptor (GPCR) biology that the alteration of even a single residue in the amino acid sequence of a particular GPCR can have a profound effect of the structure or function of that protein. As stated in the original rejection, because the instant specification does not identify those residues in SEQ ID NO:6 that are critical to the structural and functional integrity of a nicotinic acid receptor comprising that sequence, provide even a single working example of an intentionally modified protein, or identify a particular protein or group of protein for which this information is known and could be reliably applied to the instant protein by analogy, an artisan can not follow the guidance provided and alter SEQ ID NO:6 at even a single residue and predict , by resort to known scientific law, if the modified protein will produce the authentic response required to convey utility to the claimed method.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method with anything other than a native receptor protein without first making a substantial inventive contribution.

5) Claims 8 to 11 and 20 to 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record as applied to claims 8 to 11 in section 5 of the office action mailed 14 October of 2005. As stated therein, the text in paragraph 035 of the instant specification expressly states that the term "TGR183" encompasses proteins and polynucleotides "from a mammal including, but not limited to, human, mouse, rat, hamster, cow, pig, horse, sheep, or any mammal". The instant specification, however, does not provide an adequate written description of the genus of proteins encompassed by the term "TGR183" as that term is defined in the specification.

Applicant urges that they "teach the amino acid sequence of human TGR183 (SEQ ID N0:6), the nucleic acid sequence of human TGR183 (SEQ ID NO:5), and teach that other TGR183 nucleic acid and protein sequences have been described (specification, paragraph (0027)). The text in paragraph 0027 of the instant specification states that "exemplary TGR183 nucleic acid and protein sequences have been described (*see, e.g.*, WO 01/74904; WO 02/06466; US 2002052022; WO 01/87937; WO 01/73029; WO 01/77320; WO 01/36473; WO 01/36471; WO 01/98330; and WO 02/18579)". A review of each and every reference referred to shows that the only "TGR183" sequences described therein are 100% identical to SEQ ID NO:6 of the

instant application. Therefore, they do not teach "other" TGR183 proteins, they teach the same protein by different names.

Because the functional limitations "has G-protein coupled receptor activity and is activated by nicotinic acid" does not inherently flow from the structural limitations" comprises at least 70% amino acid sequence identity to SEQ ID NO:6" or "comprises at least 20 contiguous amino acids of SEQ ID NO:6", Applicant has failed to adequately described the genus of polypeptides required for the claimed method by structure, formula, chemical name, or physical properties. Simply reciting a desired functional property in conjunction with structural features that are insufficient to provide the recited function constitutes nothing more that a wish to know the identity of any compound that meets those limitations, and does not constitute an adequate written description of the required genus of molecules.

The only polypeptide molecule meeting all of the limitations of the instant claims that is described in the specification in such full, clear, concise, and exact terms as to demonstrate possession of that polypeptide comprises the entire amino acid sequence presented in SEQ ID NO:6 of the instant application, and nothing less than that entire sequence.

6) Claims 8 to 11 and 20 to 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in so far as they employ the term "TGR183" as a limitation. Because the instant specification does not identify that property or combination of properties which is

unique to and, therefore, definitive of a "TGR183" polypeptide an artisan can not determine **if a compound which meets all of the other limitations of a claim** would then be included or excluded from the claimed subject matter by the presence of this limitation. For example, it is unclear how the limitation "a nicotinic acid receptor comprising the amino acid sequence of SEQ ID NO:6" would differ in scope from the limitation "a TGR183 polypeptide comprising the amino acid sequence of SEQ ID NO:6". Applicant's position that a "TGR183" polypeptide is a polypeptide meeting all of the "defining" functional and structural limitations recited in a claim are unpersuasive simply because they ignore the very premise of the rejection. More specifically, Applicant has failed to explain how claim 8, for example, would differ in scope if the term "TGR183" were deleted therefrom. This is particularly relavent in the instant application because a protein comprising the amino acid sequence of SEQ ID NO:6 is described in at least the ten references cited in the second sentence of paragraph 0027 of the instant application, and yet, those ten different references employ a variety of different names for the protein described therein, such as GPCRx14, HM74-like GPCR, GCREC-3, etc.

7) Applicant's arguments filed 14 April of 2006 have been fully considered but they are not persuasive.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800